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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,704	05/30/2000	George Peter Lomonosoff	DOW-04647	2167

23535 7590 11/15/2005

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EXAMINER

AKHAVAN, RAMIN

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/580,704

Applicant(s)

LOMONOSSOFF ET AL.

Examiner

Ramin (Ray) Akhavan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 29 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-9 and 12-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-9 and 12-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of a response, filed 8/29/2005, amending claims 1 and 9. Claims 1, 4-9 and 12-16 are currently pending and under consideration in this action. All objections/rejections not repeated herein are hereby withdrawn. Where applicable, a response to Applicant's arguments will be set forth immediately following the body of any objections/rejections repeated herein.

As no new grounds of rejection are set forth, **this action is made FINAL.**

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 1. Claims 1, 4-9 and 12-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.**

This rejection is of record, incorporated herein and applied to the instant claims (Office Action, mailed 3/28/2005; hereinafter Action). A response to Applicant's arguments is set forth below. It is noted that the independent claims 1 and 9 are amended to limit the size of the target insert gene encoding a foreign peptide (i.e., greater than five to approximately twenty amino acids in length). However, the claims are still broad in that insertion is in *any site* of the gene encoding the plant viral coat protein in *any plant virus*. Where the dependent claims are directed to comovirus, the claims remain broad in that insertion is in *any site* of the gene encoding the plant viral coat protein.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant's assertions address each *Wands* factor respectively. A response is set forth accordingly in the order of the arguments presented.

Regarding the scope of the claims, Applicant asserts that the claims are narrower in scope. (Remarks, p. 5, last ¶). It is agreed that the amendments are narrowing in regard to the size of the insert nucleic acid. However, the claims remain of tremendously broad scope in two aspects, which two aspects are of record. First, the insertion is anywhere in the nucleic acid sequence encoding the expressed native portion of the plant viral coat protein, including where the plant virus is limited to comovirus (claims 8 and 16). Second, save claims 8 and 16, the claims are of tremendous scope because they encompass *any plant virus* or *any plant RNA virus* (claims 7 and 15).

Furthermore, Applicant asserts that the question of whether particular sequences of the native coat protein can be removed is not an issue. Indeed, it is agreed that the claims do not encompass deletion or removal of the viral coat protein or portions thereof. The salient point is not removal of sequences, but that the scope of the claims is tremendously large because target insertion is within *any site within a coat protein gene* and/or within *any plant virus*. In sum, the claimed invention remains of breadth that is deep and wide in potential insertion sites and the number of plant viruses.

Next, regarding the number of examples, Applicant asserts that there are three different examples provided. (Remarks, p. 6, ¶2). The three examples to which Applicant refers vary only insofar as three different epitopes are utilized (i.e., different inserts). Indeed, in each

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example the insertion is into the same specific site of the β B- β C loop in the coat protein of CPMV. In other words, the examples do not address unpredictability with respect to insertion (modification) in any region of the coat protein gene, or modification of any plant virus.

Regarding the amount of guidance, Applicant implies that the specification provides sufficient guidance where it teaches that exposed portions of coat proteins are to be utilized, or coat proteins having a *B*-barrel structure, as well as loops between individual strands of beta-sheet structures. (Remarks, p. 6, ¶ 3). The guidance provided is of generic nature and Applicant's assertions fail to address grounds of unpredictability set forth in the previous Action. For example, insertion of foreign nucleic acids into nonoptimal positions can lead to noninfective virus, even where the insertion is in the β B- β C loop. (e.g., *Actiokn*, p. 6, ¶ 1, *citing* Porta et al. *Virology*, 1994; 202:949-55, at 954). Therefore, even for a single plant virus insertion into other than a precise location in said loop imparts unpredictability. Of course, it must be noted that the claims are not limited to any particular site or region of the coat protein, but rather, are broadly directed to *insertion at any site*. Therefore, that the specification suggests that key insertion sites are into coat proteins having *B*-barrel structure and where insertion is into loops between individual β -sheets is of little moment, where the claims do not recite such key limitations.

Furthermore, there is unpredictability even with respect to the particular sequence(s) encoded by a given target nucleic acid insert for a given plant virus. For example, where an insert encodes an Arg-Gly-Asp motif, expression of the resulting modified coat protein resulted in particle immobilization, hence no infection. (e.g., *Action*, p. 7, first full ¶, *citing* Porta et al. 1994, at p. 954, col. 2). Thus even if insertion is into key sites within the coat protein of a given

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plant virus, there is unpredictability based on interactions resulting from expression of modified or chimeric coat proteins.

Finally, Applicant proffers a post-filing publication for support of the assertion that the level of experimentation is reasonable and that implies any results would be predictable for all plant viruses. (Remarks, p. 7, *citing* Uhde et al. 2005; 150:327-40). There appears to be some misapprehension as to what is being claimed as compared to what Uhde et al. teach. Simply put, the publication is not on point, because it does not address insertion of a target foreign protein into the viral coat protein. The reference teaches expression of a target insert as an amino-terminal extension, whereas in contrast, the instant claims are directed to insertion into the coat protein itself (e.g., insertion within a coat protein versus addition to an end of a given coat protein). Indeed, if the claims were directed to insertion of the foreign gene as an addition to the end of the coat protein, then the invention would be defined by materially and substantially distinct boundaries.

In sum, as discussed in the foregoing and for reasons of record, Applicant's assertions fail to obviate the grounds of rejection thus the claims are not supported by an enabling disclosure.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees.

See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Regarding the rejections herein below, it is noted that Applicant requests the rejections to be held in abeyance. Applicant asserts that if the claims 9 and 12-16 are otherwise allowable Applicant wishes to split out said claims into a separate application. As none of the claims are deemed allowable, Applicant's request is respectfully denied.

2. Claims 9 and 12-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,874,087.

This rejection is of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 9 and 12-16 are drawn to a genus of a method of producing a modified plant virus, while reference claims 1-9 are drawn to a species of a method of producing a modified plant virus. Species claims necessarily make obvious the broader genus claims.

3. Claims 9 and 12-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-28 of U.S. Patent No. 5,958,422.

This rejection is of record. The same analysis as above applies here. The genus claims are necessarily made obvious by the species claims.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramin (Ray) Akhavan whose telephone number is 571-272-0766. The examiner can normally be reached on Monday-Friday from 8:30-5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully submitted,

Ray Akhavan/AU 1636


DAVID GUZO
PRIMARY EXAMINER